

REMARKS

Claims 1-43 are pending in the present application.

The rejections of: (a) Claims 1-3 under 35 U.S.C. §102(b) over Town et al, (b) Claims 1-5, 9-11, 19-21, 25-27, and 42 under 35 U.S.C. §102(b) over Dormann et al, and (c) Claims 1-11, 19-27, and 42 under 35 U.S.C. §102(e) over La Rosa et al, are obviated by amendment.

Applicants submit that none of Town et al, Dormann et al, or La Rosa et al disclose or suggest a polynucleotide falling within the scope of the claimed invention. Specifically, the sequences disclosed by Town et al have 63.7% homology on a nucleotide sequence level and 71.4% homology on an amino acid level. The sequences disclosed by Dormann et al have 63.2% homology on a nucleotide sequence level and 71.1% homology on an amino acid level. Further, the sequence disclosed by La Rosa et al has 90.1% homology on an amino acid level. Evidence for the same is provided by the Sequence Alignments **submitted herewith**. In view of the foregoing, the claimed invention is not anticipated by the cited references.

Withdrawal of these grounds of rejection is requested.

The rejections of: (a) Claims 1-11, 19-27, and 42 under 35 U.S.C. §112, first paragraph (enablement), and (b) Claims 1-11, 19-27, and 42 under 35 U.S.C. §112, first paragraph (written description), are believed to be obviated by amendment.

Indeed, it is the current trend in U.S. patent examination to narrow the permissible scope of homologs when DNA or protein sequences are claimed. This case falls right in line with this trend. Nonetheless, Applicants wish to direct the Examiner's attention to a recent decision by the U.S. PTO's Board of Patent Appeals and Interferences (*Ex parte Bandman*,

enclosed herewith) in which the Board held that claims to amino acid sequences that are at least 95% homologous to the disclosed sequence are adequately described and enabled when the specification describes the nucleotide and amino acid sequences.

As in *Ex parte Bandman*, the present specification provides the amino acid sequence (SEQ ID NO: 2) and the polynucleotide encoding the same (i.e., SEQ ID NO: 1). Moreover, the claims specify the activity required for all proteins encoded by the claimed polynucleotide that fall within the scope thereof. Clearly if the Board finds that under similar circumstances to the present specification an amino acid sequence having at least 95% homology is adequately described and enabled, the certainly so too is the homology of the present application.

Further, with respect to the sufficiency of the disclosure for describing the claimed sequence, the Examiner's attention is directed to Example 14 of the Synopsis of Application of Written Description Guidelines which analyzes a situation where a claim covers a protein that is at least 95% identical to a disclosed sequence and has a specific function. In these guidelines, the Patent Office has concluded that such a claim is adequately described within the meaning of 35 U.S.C. § 112, first paragraph

There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus.

Conclusion: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.

As the specification adequately describes the sequences that at least 95% homologous to SEQ ID NO: 2, a polynucleotide that is at least 95% homologous to SEQ ID NO: 1, and the specification describes how one can test for the recited activity to readily determine whether the variants are capable of the specified catalytic activity. Therefore, the claims as presented herein are deemed to be fully described and enabled.

Withdrawal of these grounds of rejection is requested.

The rejection of Claims 1-11, 19-27, and 42 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

With respect to “stringent conditions” this language has been deleted in favor of the homology values recited in page 13, lines 19-28 used to define the “stringent conditions”. The term “gene” has been replaced with “polynucleotide”. Claims 11, 27, and 42 have been amended to ensure that all essential steps are recited.

Applicants request withdrawal of this ground of rejection.

The rejection of Claims 1-2, 11, and 27 under 35 U.S.C. §101 is obviated by amendment.

Claims 1 and 2 have been amended to define the polynucleotide as being “isolated”.

Withdrawal of this ground of rejection is requested.

The objection to the specification is obviated by the amendment to the description of Figure 4 and the submission of the enclosed substitute Sequence Listing. Applicants **submit**

herewith a substitute Sequence Listing and a corresponding computer-readable Sequence Listing. The sequence information recorded in the corresponding computer-readable Sequence Listing is identical to the paper copy of the substitute Sequence Listing. Support for all of the sequences listed in the substitute Sequence Listing is found in the present application. No new matter is believed to have been introduced by the submission of the substitute Sequence Listing and the corresponding computer-readable Sequence Listing. The specification has also been amended to add sequence identifiers where necessary. Support for this amendment is provided by the originally filed specification and Sequence Listing.

Finally, the objection to the drawings is obviated in part by amendment and traversed in part.

To address the criticism in paragraphs 5 and 6 of the Office Action, Applicants have amended the description of Figures 6-8, 10, 11, 13, and 16. Therefore, this objection is believed to be moot.

In paragraph 7 of the Office Action, the Examiner alleges that Figure 17 fails to comply with 37 CFR 1.84(g) “because it is framed”. Applicants disagree with this allegation by the Examiner. Fig. 17 shows the results of genomic Southern hybridization described in Example 8. The solid line in Figure 17 is not a “frame” as the Examiner alleges, but rather is an illustration of the outer boundary of the membrane to which the content of the electrophoretic gel was transferred. Thus, the solid line in Figure 17 is not a “frame”, but rather a part of the illustration. In view of the foregoing, Applicants submit that Figure 17 is in compliance with 37 CFR 1.84(g) and that this ground of rejection should be withdrawn.

Also, in paragraph 7, the Examiner alleges that the molecular size markers are missing for Figure 17. At the outset, it should be noted that there is no requirement in U.S.

patent practice for an electrophoretic gel to contain molecular size markers. This is especially true where the description in the specification clearly explains the detail of what is illustrated in the Figure. In this case, the description in Example 8 (see pages 44-45) sufficiently describes Figure 17 and what is shown therein. Further, the Examiner should be mindful of the fact that Figure 17 shows the results of a Southern hybridization assay where the probe is the kanamycin-tolerant (NPT) gene region of pBI121 labeled with Alphas Direct. Thus, following hybridization and detection, any molecular size markers present in the original electrophoretic gel would not be detected. In view of the foregoing, Applicants submit that Figure 17 is proper and complete.

In paragraph 8, the Examiner alleges that the molecular size markers are missing for Figure 18. This allegation is incorrect as it is noted that the molecular size markers are flanking lanes 1 and 6. Thus, this objection is without merit.

Applicants request withdrawal of these grounds of objection.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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[GENETYX-MAC : Nucleotide Sequence Homology Data]

Date : 2007.07.27

1st Nucleotide Sequence

File Name : PsUGE1
Sequence Size : 1094

2nd Nucleotide Sequence

File Name : Doremann and Bennis DNA
Sequence Size : 1356

Unit Size to Compare = 4

Pick up Location = 5

[63.2% / 1023 bp] INT/OPT.Score : < 1604/ 1836 >

```
1' ATG
61" TTTGTTCTTCTGTTGGTGGTGGTATCTAGTTTTCAAAGAATCGATTTTGCCAAGTGGGT
4' GCGATCGGCGGGGCGGAGGCCGCGGGGAGGCGGGGGCCAGCGGCCGGAGCGTGCTG
* * * * *
121" TCTTCTTGATAACCTTTCTTCTTCTTTGAAATGGGTTCTTCTGTGGAGCAGAACATTCTT
64' GTGACGGGCGGCGCGGGGTTTCATCGGCACGCACACGGCGCTGCGCCTGCTGGAGCAGGGC
* * * * *
181" GTTACTGGTGGTGGTGGCTTTATCGGGACGCATACTGTTGTTCAACTTCTCAAAGATGGT
124' TACGGCGTCACCGTCGTCGACAACCTCCACAACCTCCGTCGCCGAGGCGCTCGAACGCGTC
* * * * *
241" TTAAAGGTTTCGATCATCGATAATTTTGATAACTCTGTTATCGAAGCTGTTGATAGAGTT
184' CGCCTCATCGCCGGGCGCGCTCTCCGCCCGCCTCGACTTCATCCGGGGGGATCTGAGG
* * * * *
301" AGGGAGCTTGTTGGTCTGATCTCTCCAAGAAGCTCGACTTCAATCTGGGTGATCTAAGA
244' AGCGCCGGGGACTTGGAGAAGGCGTTTCGCGGCCAGGAGGTACGACGCCGTCGTCCTTCC
* * * * *
361" AACAAAGGGGACATTGAGAACTATTCTCCAAGCAGAGATTTGATGCTGTGATTCATTTT
304' GCGGGGCTCAAGGCCGTCGCGGAGAGCGTCGCGCGCCCGGACATGTACTACGAGAACAAAC
* * * * *
421" GCGGGTCTTAAAGCTGTGGGTGAGAGTGTTGAAAAGGGTCGCCGCTACTTTGACAATAAC
364' CTCGCCGGCACCATCAACCTCTACAAGGCCATGAACGAGCACGGCTGCAAGAAGATGGTG
* * * * *
481" TTGGTTGGAACAATCAATCTATATGAGACCATGGCAAAGTACAACTGCAAAATGATGGTG
424' TTCTCGTCGTCGCGACCGTGACGGCTGGCCGGAGGTGATCCCGTCGTCGAGGACTCC
* * * * *
541" TTTTCATCTTCTGCCACTGTTTATGGACAACCTGAAAAGATTCCATGCATGGAAGACTTT
484' AAGCTGCAGGCCGCCAACCCCTACGGCAGGACCAAGCTCATCCTGGAGGAGTTGGCGCGG
* * * * *
601" GAATTAAAGGCTATGAATCCTTATGGTCGTAAGCTCTTCTTGAAGAAATAGCTAGA
544' GACTACCAGCGCGCGGACCCGGGCTGGAGCATCGTCCTGCTGCGCTACTTCAACCCCATC
* * * * *
661" GATATTCAAAGGCAGAACCGGAATGGAGAATTATTCTGCTGAGGTACTTCAATCCTGTA
604' GGCGCCACAGCTCCGGCGAGATCGGCGAGGACCCCAAGGGGGTGCCCAACAACCTGCTG
* * * * *
721" GGAGCACATGAGAGTGGCAGTATTGGTGAGGATCCAAAAGGCATCCCCAATAACCTCATG
664' CCCTACATCCAGCAGGTCGCGCTCGGCAGGCTCCCCGAGCTCAACGTCTACGGCCACGAT
* * * * *
781" CCTTACATCCAACAAGTGGCCGTTGGACGTTTACCGGAACCTCAATGTCTATGGACATGAC
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724' TACCCACCCGTGACGGCACCGCATCAGGGACTACATACGTCGTCGACCTGGCCGAC
 ** * * * * *
 841" TATCCACCCGAGGATGGTAGTGCGGTAAGAGACTACATCCATGTGATGGATTTAGCAGAT
 784' GGGCACATCGCGGCGCTGAACAAGCTGTTGACACTCCTGATTTGCGTTGTGTGGCCTAC
 ** * * * * *
 901" GGCCATATCGCTGCGCTCAGGAAGCTATTGCTGATCCAAAGATTGGTTGTTACTGCTTAC
 844' AATCTGGGCACAGGGCGCGGCACATCCGTTCTCGAGATGGTGGCGGCGTTCAAGAAGGCA
 * * * * *
 961" AATCTAGGGACTGGTCAAGGAACGTCTGTGTTAGAAATGGTTCAGCTTTTGAAAAAGCT
 904' TCCGGCAAGGAGATCCCCACCAAGATGTGCCCCAGGAGACCGGGTGACGCGACGGAGGTT
 * * * * *
 1021" TCCGGCAAGAAAATCCCGATTAAGCTCTGTCCGAGAAGGTCAGGAGATGCAACAGCAGTT
 964' TACGCGTCCACTGAGAAGGCCGAAAGGGAGCTCGGATGGAGGGCCAGTATGGAATCGAG
 ** * * * * *
 1081" TATGCTTCAACAGAGAAGGCTGAGAAAGAACTTGGCTGGAAGGCAAAATATGGAGTGGAT
 1024' GAGATGTGCAGGGACCACTGGAAGTGGGCCAAGAAGAACCCTATGGCTACTGCGGCACT
 * * * * *
 1141" GAGATGTGCAGAGATCAGTGGAAATGGGCTTTCATAATCCATGGGGTTACCAGAATAAG
 1084' GCCGAAAAATA
 1201" CTTTGAATTTACTTCTTTTGTGGAGTTACCATTCTAATTACTCAAATCTAAAAGAAA

1st Nucleotide Sequence

File Name : PsUGE1
 Sequence Size : 1094

2nd Nucleotide Sequence

File Name : Town et al UGE DNA
 Sequence Size : 1462

Unit Size to Compare = 4
 Pick up Location = 5

[63.7% / 1023 bp] INT/OPT.Score : < 1622/ 1866 >

1' ATGGC
 121" TGTTCTTCTGTTGGTGGTGGTATCTAGTTTTCAAAGAATCGATTTTGCCAAGTGGGTTG
 6' GATCGGCGGGGCGGAGGCCGGCGGGGAGGCGCGGGGGCCAGCGGCCGGAGCGTGCTGGT
 * * * * *
 181" TTCTTGATAACCTTTCTTCTTTGAAATGGGTTCTTCTGTGGAGCAGAACATTCTTGT
 66' GACGGGCGGGCGGGGTTTCATCGGCACGCACACGGCGCTGCGCCTGCTGGAGCAGGGCTA
 * * * * *
 241" TACTGGTGGTGCTGGCTTTATCGGGACGCATACTGTTGTTCAACTTCTCAAAGATGGTTT
 126' CGGCGTCACCGTCGTCGACAACTTCCACAACCTCCGTCGCCGAGGCGCTCGAACGCGTCCG
 * * * * *
 301" TAAGGTTTCGATCATCGATAATTTTGATAACTCTGTTATCGAAGCTGTTGATAGAGTTAG
 186' CCTCATCGCCGGGCGCGCTCTCCGCCCCGCTCGACTTCATCCGGGGGGATCTGAGGAG
 * * * * *
 361" GGAGCTTGTTGGTCTGATCTCTCCAAGAAGCTCGACTTCAATCTGGGTGATCTAAGAAA
 246' CGCCGGGGACTTGGAGAAGGCGTTCGCGGCCAGGAGGTACGACGCCGTCGTCCACTTCGC
 * * * * *
 421" CAAAGGGGACATTGAGAACTATTCTCCAAGCAGAGATTTGATGCTGTGATTCTTTTGC

Date : 2007.07.26

4

Date : 2007.07.27

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- File Name      : PsUGE1TRANSLATE
Sequence Size    : 364

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File Name      : Doremann bennig translate
Sequence Size  : 351
```

```
Unit Size to compare = 2
Pick up Location      = 5
```

INT/OPT.Score : < 1348/ 1356 >

1" MGSSVEQNILVTGGAGFIGTHTVVOLLKDGFKVSIIDNFDNSVIEAVDR

50" VRELVGPDLSKKLDFNLGDLRNKGDIEKLFSKORFDAVHFAGLKAVGESVEKGRRYFDN

110" NLVGTINLYETMAKYNCKMMVFSSSATVYGOPEKIPCMEDFELKAMNPYGR TKLFLEEIA

170" RDIOKAEPWRIILLRYFNPVGAHESGSIGEDPKGIPNNLMPYIOOVAVGRLPELNVYGH

230" DYPTEDGSAVRDYIHVMDLADGHIAALRKLEADPKIGCTAYNI GTGOGTSVI EMVAAFEK

290" ASGKKIPIKLCPRRSGDATAVYASTEKA EKELGWKAKYGVDEMCRDOWKWA FENNPWGYON

361' TAEK

350" KL

```
File Name      : PsUGE1TRANSLATE
Sequence Size  : 364
```

```
File Name      : Town et al. UGE
Sequence Size  : 351
```

```
Unit Size to compare = 2
Pick up Location      = 5
```

INT/OPT.Score : < 1358/ 1366 >

1" MGSSVEQNILVTGGAGFIGTHTVVQLLKDGFKVSIIDNFDNSVIEAVDR

[GENETYX-MAC: Multiple Alignment]

Date : 2007.07.27

PsUGE1amino acids	1	MAIGGAEAGGGGAGASGRSVLTGGAGFIGHTHTALRLLEQGYGMTVVDNFHNSVPEALER	60
Town et al. UGE amino acids	1	-----MGS---SVEQN-ILVTGGAGFIGHTHTVQLLKDGFKMSIIDNFDSVIEAVDR	49
Doremann& Bennis amino acids	1	-----MGS---SVEQN-ILVTGGAGFIGHTHTVQLLKDGFKMSIIDNFDSVIEAVDR	49
Rosa Patent amino acids	1	MAIGGSEAGGGGAGSMR-SVLTGGAGFIGHTHTVLRLEQGTITTVVNFHNSVPEALDR	59
PsUGE1amino acids	61	VRL-IAGPALSARLDFIRGDLRSAGDLEKAFPAARRYDAVVF-FAGLKAVGESVARPDMYY	118
Town et al. UGE amino acids	50	VRELV-GPDL SKKLDFNLGDLRNKGDIKLFISKQRFDAVIH-FAGLKAVGESVENBRRMF	107
Doremann& Bennis amino acids	50	VRELV-GPDL SKKLDFNLGDLRNKGDIKLFISKQRFDAVIH-FAGLKAVGESVEKGRMY	107
Rosa Patent amino acids	60	VRL-IAGPALSTRLDFIRGDLRNTDLEKVEAARRYDAVIHPFAGLKAVGESVAHPEMY	118
PsUGE1amino acids	119	ENNLIACTINLYKAMNEHGCKKMFVSSSATVYQWPEVTPQVEDSKLQANPYGRTKLILEE	178
Town et al. UGE amino acids	108	DNNLVGTINLYETMAKYNCKMMVFSSSATVYGOPEKIPQMEDFELKAMNPYGRTKLFLEE	167
Doremann& Bennis amino acids	108	DNNLVGTINLYETMAKYNCKMMVFSSSATVYGOPEKIPQMEDFELKAMNPYGRTKLFLEE	167
Rosa Patent amino acids	119	ENNLIGTINLYKSMKEHGCKKLVFSSSATVYQWPEVTPQVEDSKLQANPYGRTKLILED	178
PsUGE1amino acids	179	LARDYVRADPGWSTVLLRYFNPIGAHSGEIGEDPKGVNNLLPYIQQVAVGRLPELNVY	238
Town et al. UGE amino acids	168	IARDIQKAEPEWRITILLRYFNPIGAHSGEIGEDPKGIPNNLMPYIQQVAVGRLPELNVY	227
Doremann& Bennis amino acids	168	IARDIQKAEPEWRITILLRYFNPIGAHSGEIGEDPKGIPNNLMPYIQQVAVGRLPELNVY	227
Rosa Patent amino acids	179	MARDYHRADEWSTVLLRYFNPIGAHSGEIGEDPKGIPNNLLPYIQQVAVGRLPELNVY	238
PsUGE1amino acids	239	GHDYPTRDGTAIRDYIHVVDLADGHIAALNKLHDPDFGQVAYNLGTGRGTSVLEMVAAF	298
Town et al. UGE amino acids	228	GHDYPTEDGSAVRDYIHVMDLADGHIAALRKLHADPKIGCTAYNLGTGGTSVLEMVAAF	287
Doremann& Bennis amino acids	228	GHDYPTEDGSAVRDYIHVMDLADGHIAALRKLHADPKIGCTAYNLGTGGTSVLEMVAAF	287
Rosa Patent amino acids	239	GHDYPTRDGTAIRDYIHVVDLADGHIAALNKLHDSDFGQVAYNLGTGRGTSVLEMVAAF	298
PsUGE1amino acids	299	KKASGKEIPITKMCPRRPGDATEVYASTEKAERELGWRAYGYIEEMCRDOWNWAKKNPYG-	357
Town et al. UGE amino acids	288	EKASGKKIPIKLCPRRSGDATAVYASTEKAERELGWKAKYGVDEMCRDQWKWANNPNWGY	347
Doremann& Bennis amino acids	288	EKASGKKIPIKLCPRRSGDATAVYASTEKAERELGWKAKYGVDEMCRDQWKWANNPNWGY	347
Rosa Patent amino acids	299	KKASGKEIPITKLCPRRPGDAT-EVYASTEKAERELAWRAYGYIEEMCRDOWNWAKKNPYG-	356
PsUGE1amino acids	358	--YCGTAEK	364
Town et al. UGE amino acids	348	QNKL-----	351
Doremann& Bennis amino acids	348	QNKL-----	351
Rosa Patent amino acids	357	--YCGGAKK	363